

Actus FOUNDATION

Amanda's Way

July 16, 2018

Chairwoman DeGette, and all distinguished members:

We represent The Actus Foundation, which was founded after the death of our beloved daughter Amanda to Fentanyl Toxicity on January 11, 2018. While our Foundation sees substantial reason for hope regarding our nation's present Opioid Crisis ("The Crisis") within the present Administration and Congress, we also see the warning signs of conditions ahead which may encourage a politically based response on the part of some Lawmakers. We would like to detail some of these hopeful signs, as well as our concerns, for your consideration.

A. Some Background Facts:

- 1) In 2013, a deadly group of chemicals entered the US illicit drug supply stream and began to ravage numerous user groups within The Crisis. These chemicals, properly named "Synthetic opioids", are generically referred to by their summary moniker, Fentanyl. Fentanyl is indeed a "synthetic opioid", but there are many sub-chemicals related to Fentanyl ("analogues") in the market, as well as numerous other compounds, such as the "U" series and various analogues of the drug *Bucinnazine*.

All these synthetic opioids are of grave concern. We are wary of the tendency to lump all under the term "Fentanyl", as it may tend to simplify the issue in people's minds. Fentanyl is the lion's share of what arrives on our shores, but it is by no means the only one.

- 2) Synthetic Opioids are a grave threat for several reasons:

- a. As synthetic chemicals, they can be made without the tedium of growing plants and extracting their natural chemicals. Synthetics can be made clandestinely from very simple "precursor" chemicals in a laboratory. It should be noted that a synthetic chemical can be made from any number of recipes, rendering authorities incapable of consistently tracking the necessary precursors as a means of restricting manufacturing.

Controlling heroin is aided by the need of acres of poppy fields which are visible by any number of means. Synthetic opioid manufacturing is relatively undetectable as there are no natural plants involved, and recipes can be updated frequently to avoid detection by tracking of precursors.

- b. As synthetic chemicals, endless versions of the chemical can be spun-out with insignificant differences in what they do, but significant differences in their chemical structure, rendering them outside the reach of DEA Scheduling (why passage of SITSa is urgently important). At present, there are >1,900 analogues calculated just for Fentanyl, of which we have only documented 18. This means that each time DEA works through the process of scheduling the 19th, 20th, etc., the manufacturers can introduce yet another analogue. Without SITSa, they can play that game as long as it takes DEA to schedule 1,882 more analogues, one at a time.

- c. The key danger is that these synthetics, especially Fentanyl, which is the dominant synthetic in the market now, **are significantly more potent** than their natural, plant-based cousins. The relative potency is not controllable under the present scheme of distribution. The dealers do the mixing and their ability to make a 100:1 ratio mix with any degree of consistency (what we call in pharma “homogeneity”) is non-existent. Therefore, we can roughly say that every time a pure Fentanyl batch is mixed – without any natural heroin – approximately 20% of the retail-level doses will produce fatalities.

The only thing preventing 20% of *all* street-opioid from producing fatal results, is that most of the drugs being seized at this time are a mixture of natural and synthetic because the mix makes for the “best product” from the *user’s* perspective. However, the “best product” from the *dealer’s* perspective is pure Fentanyl. Our Foundation uses historical business modelling to predict that it is the dealer’s perspective which really matters, and that this means Fentanyl will indeed displace heroin – **completely** – at some future point. The 20% deadliness of that drug means that we will see death rates of >300,000/annum once that displacement is fully executed. The displacement of heroin by Fentanyl, et al, is a certainty which is well under way.

- d. They are Narcan resistant. Narcan has been saving thousands of lives in this crisis, but Fentanyl’s strength and unique interaction with the body demands more doses, delivered intermittently. In fact, one of the analogues appearing in 2017 (acryl fentanyl) was the subject of a myth that it was “Narcan-proof” and was later the subject of a clarification memo by DHS (11 July 2017). In that memo, DHS claims there “are no fentanyl analogues resistant to Naloxone”. This is a matter of semantics. From the perspective of first-responder or medical personnel, **all** fentanyl analogues are *resistant* to Naloxone (Narcan).
- e. Unlike all illicit drugs which have fed this waxing Crisis throughout the decades, none of them has had the terror implications of Synthetic Opioid. From their appearance on the scene during the Moscow Theater Incident (Remifentanyl), to the devastation they have wrought in this country since their sudden appearance in 2013, these chemicals have certainly caught the attention of terror groups. Most security people we talk to say the question is not one of “if”, but one of “when”.

We have asked the question of many of these experts why it has yet to happen. There is no clear answer, but the best we’ve heard is that they are waiting for an analogue which is so Narcan-resistant as to be, de facto, Narcan-*proof*. Reminder: We have at least 1,882 more analogues for them to choose from.

- 3). Synthetic Opioid Death is dramatically under-reported. While CDC publishes 72,000 as the number who died in 2017 from OD, there are numerous jurisdictions where Medical Examiners forego the cost, tedium and delay of toxicology, which is required to call a manner of death “drug poisoning”. In such cases, an OD is declared “natural causes”. It is estimated that this is a 30-50% occurrence. This puts the true death number at 100,000. This is close to 2 Vietnams each year.

B. Our Position

Our Foundation raises these facts, and the displacement dynamic, to the level of a true *paradigm change* in the world of illicit drug distribution and use in America. Paradigm is an overused word in our sensationalized culture, but we use the phrase *paradigm shift* in the scientifically disciplined spirit intended by the term's key developer, Thomas Kuhn. A paradigm shift, what Immanuel Kant described as a "revolution of the way of thinking", demands revolutionary methods.

We need to act differently at the federal, international level to defer the displacement date as far in the future as possible, and then develop revolutionary thinking at all levels to help reduce the dreadful effects of The Crisis.

What do we need to do?

- 1) While dealing and using drugs are a very *difficult* problem to solve, the sudden and massive introduction of Fentanyl and other synthetics has created a problem which is as *simple* as it is *difficult*. All Fentanyl comes from China, for many very good reasons. These reasons are detailed by our Foundation and need not be detailed here. Suffice it to say, China will remain the dominant, virtually sole, manufacturer of America's illicit Fentanyl for the foreseeable future. The simplicity of that fact presents a window of opportunity.
- 2) We need to get Law Enforcement (LE) re-engaged. Numerous District Attorneys throughout the country have demanded Law Enforcement cede drug scene responses to HazMat due to the potential of synthetic opioid at any drug scene. While this reaction was prudent at one time, there are tools available now which give us the ability to protect officer safety. Only by re-engaging Law Enforcement will we be able to mount the control processes we need to handle this crisis.

For those legislators who immediately associate re-engagement of Law Enforcement as a restart of the "war-on-drugs" we can assure you that nothing could be farther from the truth. In our years of traveling the country and training narcotics-based Law Enforcement groups of all levels, one thing is immediately clear: We have yet to meet a single narcotics officer, at any level, who thinks locking up users and low-level dealers provides any value. "We cannot arrest our way out of this problem" has been fully accepted and endorsed by all Law Enforcement resources our Foundation has worked with.

C. Hopeful Signs

- 1) President Trump repeatedly discusses the issue and has raised it with GS Xi Jinping directly. This is encouraging, although we believe the discussions and actions thus far fall short of any tangible benefit (the May 1 law in China is valueless); but at least the discussion has opened.
- 2) Law Enforcement sees the need to deal with this Crisis at the distribution level, and universally sees addicts/users as the true victims they are.

- 3) Narcan as social responsibility. There are several unintended negative consequences of our nation's quick response of making Narcan readily available, but each use saves a life! The Surgeon General compares Narcan to the Heimlich maneuver or CPR. This is tremendously encouraging.
- 4) Passage of the INTERDICT and STOP Acts in the last Congress.
- 5) Introduction of SITSA and POWER acts in the last Congress.
- 6) The empaneling of *victims* of The Crisis by E&C Committee Chairman during the 115th Congress in anticipation of legislative activities. We recommend the 116th E&C Chairman do the same.
- 7) Myth/stigma-free discussions of the benefits of Medically Assisted Treatment (MAT)
- 8) Myth/stigma-free discussion of controversial harm-reduction concepts such as safe-shooting sites
 - a. The Actus Foundation is not here endorsing any specific harm-reduction method, but merely applauding the willingness to discuss any and all potential solutions.

D. Risks of politicizing

We turn to risks we see on the horizon. While response to The Crisis has mostly been non-partisan, there have been moments where certain lawmakers have behaved as political animals to the detriment of the dying children of The Crisis, which includes our daughter, Amanda Beatrice Rose (†2018):

- 1) Many lawmakers have been applauding the passage of a law (in China) making Fentanyl manufacturing a felony. As any businessman knows, the law in China is only worth the Party's willingness to enforce. Applauding this law as productive without GS Xi's personal commitment to do something productive with that law, will not move the needle one iota. We believe lawmakers know this, and their exuberance about the law is for show.
- 2) The same applies to the Southern Border. It is encouraging that we passed laws dealing with the USPS's place in The Crisis last year, and we are likewise encouraged that Mr. Barksdale is testifying today on what has developed within that context. We believe we should all recognize that the USPS, and other delivery services, are used to bring in kilotons of this poison, and that a myopic focus on the place of the Southern Border in The Crisis is a statement for political populism, for which there is no place when 100,000 young Americans are dying each year.
- 3) When SITSA was presented to the 115th Congress, it passed the house overwhelmingly – and generally without partisanship. However, two nights before the vote in the Senate, there was a criminally irresponsible article published in the Washington Post, which was devoid of facts, and only contained comment by one-sided extremists. Yet, that article and its use of the term “war-on-drugs” was enough to cause Senators on both sides of the aisle to abandon the provision, and STOP Act was sent to the President without the most important provision it contained. We wish we could figure a way to calculate how many young people died due to that disgraceful turn of events. If we could, it might serve as a sobering warning to avoid politics and just do the right thing.

E. Summary

The reason for concern is that this is perhaps the greatest threat to our country since the cold war. Moreover, the combination of The Opioid Crisis and the rising of anti-American hate around the world are converging at a nexus where Fentanyl/Synthetic Opioid is waiting like a spark for a tinder box.

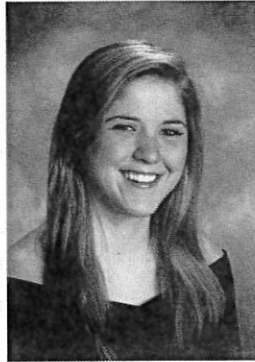
For instance, if we play partisan politics with the “war-on-drugs”, and dismiss out of hand any significant penalty increases intended to treat these chemicals as the WMDs that they are, we will allow the terrorists, who are surely watching what we do, to work out plans to exploit the greatest weapon they’ve ever known. Our Foundation has facts and figures to justify “Fentanyl Specific Legislation” as means to distinguish dealing in these chemicals from dealing in all other illicit drugs, because it is far more than a drug. Our position on this is easily dismissed as a redo of the “war-on-drugs” by people who want to politicize. However, how would they explain our position that penalties for all other “drugs” should be *reduced* since we believe that the war-on-drugs has clearly been ineffective. Yet, we seem to be much more effective at fighting terrorism, and Fentanyl will be a terrorist tool soon.

Perhaps more terrifying than anything else we see in The Crisis at this moment is an article in the WSJ (June 26, 2018) that provisional data shows that the US may see our first reduction in drug death in 20 years for the Y-O-Y period of 2017-2018. This is very clearly a false reduction in The Crisis caused by the masking characteristic of Narcan (one of the unintended negative consequences referred to above). While this is indeed a reduction in death and, as such, is indescribably valuable to the families spared of the death of their loved ones, it is a false reduction in the extent of The Crisis.

We explain: The only metric for deciding whether The Crisis is increasing, or decreasing is OD rates – fatal and non-fatal. How many kids are dying may be nothing more than an indication of how much Narcan is out there. How many are *overdosing*, whether they survive or not, tells us how bad the problem is in real terms. Therefore, we support an aggressive deployment of OD MAP Software.

If death data showing a nominal reduction is used by politicians to declare victory, we run the risks of taking our foot off the accelerator. That would indeed be tragic, since we have barely gotten geared up to take this problem on, and we have yet to find our footing with solutions for the new paradigm.

The Actus Foundation



The Founders of The Actus Foundation are Michael and Nancy Gray. The Grays are the parents of Declan Gray, 24, and Amanda Rose Gray, who was killed by a poisoning of straight Fentanyl on January 11, 2018 at the age of 24. The Gray family battled with acute mental illness throughout Amanda's life, and intermittent substance abuse in the last year before her passing.

Michael and Nancy founded The Actus Foundation, a 501(c)(3) charitable organization, in 2018. Our Foundation's purpose is to advocate for solutions for the forgotten mentally ill in the United States. While our country boasts a medical science infrastructure which is the envy of all the world, our treatment of the mentally ill, nascent as it was in the late 20th century, has since reverted a true state of antiquation. America's medical science is the fair-haired child we proudly show-off to the world, while behavioral science is something we sheepishly hide in the closet.

At present, one of the greatest threats to the mentally ill in America is the surge of dangerous synthetic opioids into our country's illicit drug market. The Actus Foundation advocates for solutions to treating the entirety of the overdose epidemic problem in America, including the largely forgotten constituency of *intermittent* users. Most notable among them are acutely mentally ill, who abuse opioids or other drugs (prescription and non-prescription) to the point of addiction and death in their search for symptom relief from tragically under-treated, and often undiagnosed, diseases.

The introduction of Fentanyl into the supply stream means all aspects of illicit drug use must be considered to save lives, since any single instance of illicit opioid use may lead to death. The time to see the threat as related only to addicts is long past. Michael Gray is a popular speaker, offering unique analyses and suggestions for creative solutions to a new problem, i.e., an old problem with a recently altered paradigm. Michael walks participants through the murky world of the drug problem clarifying the threat and dispelling myths.